NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH

Notice of Public Hearing and Opportunity to Comment on
Proposed Amendments to Article 13 of the New York City Health Code

What are we proposing? The Department of Health and Mental Hygiene ("Department") is proposing that the Board of Health ("Board") amend Article 13 (*Clinical Laboratories*) of the New York City Health Code ("Health Code") to enhance certain disease reporting requirements.

When and where is the hearing? The Department will hold a public hearing on these proposed rules. The public hearing will take place at 10:00AM to 12:00PM on Monday, November 27, 2023. The hearing will be conducted by video conference accessible via internet or telephone:

- **Internet:** To participate in the public hearing, enter to register at this Webex URL: https://nycdohmh.webex.com/nycdohmh/j.php?MTID=m9d5d5a7926b23c833ef35ff824a597e1
  If prompted to provide an event number or password, enter the following:
  Event number: **2345 137 7914**, Password: **Health** (432584 from phones and video systems)
- **Phone:** For access, dial: (408) 418-9388; (646) 992-2010 (New York City) and enter the following Access code: **234 513 77914**, Password: **Health** (432584)

How do I comment on the proposed rules? Anyone can comment on the proposed rules by:

- **Website:** You can submit comments to the Department through the NYC Rules website at http://rules.cityofnewyork.us.
- **Email:** You can email written comments to resolutioncomments@health.nyc.gov.
- **Mail:** You can mail written comments to:
  New York City Department of Health and Mental Hygiene
  Gotham Center, 42-09 28th Street, CN 30
  Office of General Counsel
  Attn: Svetlana Burdeynik
  Long Island City, NY 11101-4132
- **Fax:** You can fax written comments to the Department at (347) 396-6087.
- **Speaking at the hearing:** Anyone who wants to comment on the proposed rules at the public hearing must sign up to speak. You can sign up before the hearing by calling Svetlana Burdeynik at (347) 396-6078 or by emailing at resolutioncomments@health.nyc.gov before the hearing begins at 10:00AM on November 27, 2023. While you will be given the opportunity during the hearing to indicate that you would like to comment, we prefer that you sign up in advance. You can speak for up to three minutes.

Is there a deadline to submit written comments? Written comments must be received on or before November 27, 2023 at 5:00 p.m.

Do you need assistance to participate in the hearing? You must tell us if you need a reasonable accommodation of a disability at the hearing. You must tell us if you need a sign language interpreter. You

can tell us by mail at the address given above. You may also tell us by telephone at (347) 396-6078. You must tell us by November 13, 2023.

Can I review the comments made regarding the proposed rules? You may review the online comments made on the proposed rules at https://rules.cityofnewyork.us/proposed-rules/. All written comments and a summary of the oral comments received by the Department will be made available to the public within a reasonable period of time after the hearing by the Department's Office of General Counsel.

Where can I find the Department's rules? The rules of the Department can be found in Title 24 of the Rules of the City of New York.

What rules govern the rulemaking process? This notice is made according to the requirements of New York City Charter ("Charter") § 1043. These proposed rules were included in the Department's fiscal year (FY) 2023 regulatory agenda.

Statement of Basis and Purpose

The Department's Division of Disease Control conducts disease surveillance and control activities for most of the diseases required to be reported pursuant to Article 11 (Reportable Diseases and Conditions) of the Health Code. The Division of Disease Control also enforces Article 13 (Clinical Laboratories) of the Health Code, which regulates the performance of laboratory tests and reporting of test results. In addition, the Department is required to comply with various provisions of Part 2 of the New York State Sanitary Code, found in Title 10 of the New York Codes, Rules and Regulations, with respect to control of communicable diseases.

To conduct more effective, timely and complete disease surveillance and control, the Department is proposing that the Board amend Article 13 of the Health Code as described below.

Syphilis reporting

The Department is requesting that the Board amend Health Code § 13.03(b)(2) to require laboratories to report all negative syphilis test results and to simplify reporting requirements when laboratories perform required follow-up testing. The Health Code currently requires the reporting of all positive and indeterminate syphilis test results, but only some negative syphilis test results. Collecting all negative syphilis test results will improve diagnosis and treatment of patients and their sexual partners.

In 2021, there were 9,965 reported cases of syphilis among New York City residents. Without appropriate treatment, syphilis can damage the heart, brain and other organs and can be life-threatening. Testing and diagnosis of syphilis is complex. Accurate diagnosis often requires an assessment of multiple types of tests and a review of testing history to determine whether a patient is currently infected and, if they are, their disease stage and treatment regimen. Without knowledge of prior negative test results, a reinfection can be misinterpreted as evidence of prior infection, delaying treatment and increasing the risk of disease progression, poor health outcomes and disease transmission. Since a syphilis diagnosis triggers contact tracing (notifying sexual partners and offering testing), delays in diagnosis can also impact partners' health and further increase the risk of onward transmission.

In addition, having all negative syphilis test results would allow the Department to monitor compliance with the Health Code requirement for providers to test pregnant persons for syphilis during 28 to 32 weeks of pregnancy (*see,* Health Code § 11.33). This requirement was added to the Health Code in 2019 to reduce the risk of congenital syphilis, which is preventable with timely identification and treatment of syphilis in the pregnant person. Reporting of all syphilis test results would allow the Department to identify providers in need of education regarding the testing requirement, thus advancing efforts to reduce cases of congenital syphilis in New York City. Having negative test results would also help the Department monitor whether infants exposed to syphilis receive appropriate follow-up testing, consistent with Centers for Disease Control and Prevention guidelines.

The Department also proposes additional changes to simplify reporting requirements where follow-up syphilis testing is performed following an indeterminate test result. With reporting of all syphilis test results, separate reporting rules will not be needed when specimens are referred to another laboratory for additional testing. This reporting change will streamline reporting for laboratories and improve reporting accuracy.

Hepatitis B Reporting

The Department is requesting that the Board amend Heath Code § 13.03(b)(3)(B) to require laboratories to report all hepatitis B e antigen and all hepatitis B surface antigen test results, including negative and indeterminate results. The Health Code currently requires, pursuant to § 13.03(a), the reporting of all positive test results for any disease or condition required to be reported pursuant to Article 11, including hepatitis B. Additionally, the Health Code currently requires, pursuant to § 13.03(b)(3)(B), laboratories to report all hepatitis B DNA test results, including positive, negative and indeterminate results, and further requires laboratories to report all hepatitis B surface antigen and hepatitis B surface antibody test results for children under 5 years of age when patient age is known. Requiring the reporting of all hepatitis B surface antigen test results for all ages, as well as all hepatitis B e antigen test results, will improve individual patient outcomes and decrease hepatitis B morbidity and mortality in New York City.

More than 243,000 people are living with chronic (active) hepatitis B in New York City, with 5,346 new cases reported in 2021. Most people who acquire hepatitis B infection as adults will clear the virus on their own, but many will progress to chronic hepatitis B, which can lead to serious health issues, including cirrhosis and liver cancer. All people with chronic hepatitis B require engagement in care and regular monitoring for liver damage and other complications; a subset require treatment with antiviral medications.

Hepatitis B e antigen and hepatitis B surface antigen testing are used to diagnose hepatitis B infection and determine whether a person has chronic infection requiring treatment. Hepatitis B e antigen and hepatitis B surface antigen testing may also be used for people already diagnosed with chronic hepatitis B, including for disease monitoring, providing important information on infectiousness and treatment eligibility, and case classification by the Department.

Without negative hepatitis B e antigen and hepatitis B surface antigen test results, the Department has limited knowledge regarding follow-up testing and treatment of people who have tested positive for

hepatitis B. Reporting of negative hepatitis B e antigen and hepatitis B surface antigen test results will allow the Department to better estimate the proportion of New Yorkers with hepatitis B infection who are appropriately tested and linked to care, identify gaps in access to care, develop targeted interventions to increase linkage to care and improve provider knowledge of hepatitis B testing and treatment guidelines, and increase disease monitoring.

Hepatitis C Reporting

The Department is also requesting that the Board amend Heath Code § 13.03(b)(3)(C) to require laboratories to report all hepatitis C antibody test results, including positive, negative and indeterminate results. The Health Code currently requires laboratories, in addition to reporting all positive hepatitis C test results pursuant to § 13.03(a), to report all hepatitis C nucleic acid amplification test results. Requiring the additional reporting of all hepatitis C antibody test results will improve individual patient outcomes and decrease hepatitis C morbidity and mortality in New York City.

More than 86,000 people are living with chronic hepatitis C in New York City, with 2,832 new cases reported in 2021. Approximately 15% of people with hepatitis C will clear the virus on their own, but most will develop chronic hepatitis C, which can lead to serious health issues, including cirrhosis and liver cancer if left untreated. Identification of acute hepatitis C infection (infection within six months following exposure to the virus) allows an opportunity to recognize and break chains of hepatitis C transmission. However, of the 2,832 cases of hepatitis C reported to the Department in 2021, only 130 were identified to be acute infections through resource-intensive case investigation.

Hepatitis C antibody testing is an initial screening test to determine whether a person has a current or prior hepatitis C infection, which should be followed by a confirmatory hepatitis C RNA test. More complete detection of acute infection at the population level could be made possible by identifying people who had a negative hepatitis C antibody test with a subsequent positive hepatitis C antibody test within 12 months. Such a pattern would indicate seroconversion and recent infection, which would prompt the Department to investigate the transmission event and engage the individual in care. Reporting of negative hepatitis C antibody results will thus allow the Department to better recognize recent hepatitis C transmission and detect clusters, improve its understanding of hepatitis C disease burden in New York City, identify inequities in hepatitis C screening to inform targeted outreach and other public health interventions, and support earlier linkage to care, treatment and cure for people with recent infection, thereby reducing the risk of transmission.

Statutory Authority

The authority for these proposed amendments to the Health Code is found in sections 556, 558 and 1043 of the Charter. Section 556 of the Charter provides the Department with jurisdiction to regulate all matters affecting health in New York City. Section 558 of the Charter empowers the Board to amend the Health Code and to include all matters to which the Department's authority extends. Section 1043 grants the Department rule-making authority. Further, New York State Public Health Law § 580(3)(a) authorizes the Department "to enact or enforce additional laws, codes or regulations affecting clinical

laboratories…related to the control, prevention or reporting of diseases or medical conditions or to the control or abatement of public health nuisances."

The proposed amendments are as follows:

Note:
Text in [brackets] is to be deleted.
Text underlined is new.
Asterisks (***) indicated unamended text.

"Shall" and "must" denote mandatory requirements and may be used interchangeably unless otherwise specified or unless the context clearly indicates otherwise.

RESOLVED, that the section heading and subdivision (b) of section 13.03 of Article 13 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, are amended to read as follows:

§ 13.03 Report of Findings, Supplemental Testing[,] and Submission of Isolates.

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(b) (1)

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(2) With regard to syphilis[, in addition to reporting any positive or reactive test results, any treponemal or non-treponemal results, whether qualitative or quantitative, shall be reported to the Department, and additional testing must be performed and the results reported, as follows]:

(A) [Any negative or non-reactive test results, or any quantitative results, on syphilis tests associated with positive or reactive results] All syphilis test results, whether positive, negative or indeterminate, shall be [separately] reported to the Department. For purposes of this paragraph, syphilis tests include, but are not limited to, treponemal tests, non-treponemal tests and direct detection tests, such as darkfield microscopy, direct fluorescent antibody and polymerase chain reaction tests.

(B) Where the result of a treponemal or non-treponemal syphilis test is indeterminate, the laboratory must [report the indeterminate test result to the Department] perform additional testing as provided herein. For purposes of this [subsection (b)(2)] subparagraph, an indeterminate test result is one in which the result of a test is weakly reactive, minimally reactive, equivocal, inconclusive, or otherwise indeterminate; an indeterminate result does not include instances where two separate tests have conclusive but discordant results.

i. When a treponemal test result is indeterminate, the laboratory must perform, or refer the specimen to another laboratory for the performance of, a second treponemal test on the same specimen using an alternate treponemal test within 24 hours of obtaining the indeterminate result [and report the results of that second test to the Department]. Where the result of the second treponemal test is also

indeterminate, whether performed by the same laboratory or a different laboratory, no additional treponemal test is required.

ii. When a non-treponemal test result is indeterminate, the laboratory must perform, or refer the specimen to another laboratory for the performance of, a second non-treponemal test on the same specimen using the same or an alternate non-treponemal test within 24 hours of obtaining the indeterminate result [, and report the results of that second test to the Department]. Where the result of the second non-treponemal test is also indeterminate, whether performed by the same laboratory or a different laboratory, no additional non-treponemal test is required.

[(C) If a laboratory has been referred a specimen to perform only tests associated with a positive result or an indeterminate result obtained at the referring laboratory, and such associated syphilis tests have yielded only negative or non-reactive results, then only the referring laboratory shall report said negative or non-reactive results to the Department within 24 hours of obtaining the results from the testing laboratory.

(D) If a laboratory obtains negative or non-reactive results or an indeterminate result on a specimen submitted for syphilis testing and refers a specimen for further syphilis testing to another laboratory, and such further syphilis tests yield positive or reactive results, then, in addition to the testing laboratory reporting such positive or reactive results, the referring laboratory shall report both the negative or non-reactive results or indeterminate result obtained by it and also the positive or reactive results of any such further syphilis testing within 24 hours of obtaining the results from the testing laboratory.

(E) If a laboratory has been referred a specimen to perform only tests associated with an indeterminate result obtained at the referring laboratory, and such associated syphilis tests have yielded only indeterminate results, then, in addition to the testing laboratory reporting such indeterminate results, the referring laboratory shall report both the indeterminate result obtained by it and also the indeterminate results of such further syphilis testing within 24 hours of obtaining the results from the testing laboratory.]

(3) (A)

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(B) With regard to hepatitis B, all <u>hepatitis B</u> DNA<u>, hepatitis B e antigen and hepatitis B surface antigen</u> test results must be reported, including positive, negative[,] and indeterminate results. In addition, all [hepatitis B surface antigen and] hepatitis B surface antibody test results, including positive, negative[,] and indeterminate <u>results</u>, for children ages 0 days to 1,825 days (birth up to the fifth birthday) must be reported electronically in accordance with subdivision (c) of this section when patient age is known. Blood bank laboratories and other laboratories that perform hepatitis B DNA<u>, hepatitis B e antigen or hepatitis B surface antigen</u> tests on donated blood are exempt from reporting negative and indeterminate hepatitis B DNA<u>, hepatitis B e antigen or hepatitis B surface antigen</u> test results for such donated blood.

(C) With regard to hepatitis C:

(i) All hepatitis C nucleic acid amplification and hepatitis C antibody test results, including [both] positive, [and] negative and indeterminate results, must be reported electronically in accordance with subdivision (c) of this section. Blood bank laboratories and other laboratories that perform hepatitis C nucleic acid amplification and hepatitis C antibody tests on donated blood, without a positive hepatitis C antibody test, are exempt from reporting negative hepatitis C nucleic acid amplification or hepatitis C antibody test results for such donated blood.

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NEW YORK CITY MAYOR'S OFFICE OF OPERATIONS
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CERTIFICATION / ANALYSIS
PURSUANT TO CHARTER SECTION 1043(d)

RULE TITLE: Amendment of Laboratory Reporting Requirements (Health Code Article 13)

REFERENCE NUMBER: 2023 RG 084

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has analyzed the proposed rule referenced above as required by Section 1043(d) of the New York City Charter, and that the proposed rule referenced above:

(i) Is understandable and written in plain language for the discrete regulated community or communities;

(ii) Minimizes compliance costs for the discrete regulated community or communities consistent with achieving the stated purpose of the rule; and

(iii) Does not provide a cure period because it does not establish a violation, modification of a violation, or modification of the penalties associated with a violation.

/s/ Grace M. Francese — *October 19, 2023*
Mayor's Office of Operations — Date

NEW YORK CITY LAW DEPARTMENT
DIVISION OF LEGAL COUNSEL
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212-356-4028

CERTIFICATION PURSUANT TO

CHARTER §1043(d)

RULE TITLE: Amendment of Laboratory Reporting Requirements (Health Code Article 13)

REFERENCE NUMBER: 2023 RG 084

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has reviewed the above-referenced proposed rule as required by section 1043(d) of the New York City Charter, and that the above-referenced proposed rule:

(i) is drafted so as to accomplish the purpose of the authorizing provisions of law;

(ii) is not in conflict with other applicable rules;

(iii) to the extent practicable and appropriate, is narrowly drawn to achieve its stated purpose; and

(iv) to the extent practicable and appropriate, contains a statement of basis and purpose that provides a clear explanation of the rule and the requirements imposed by the rule.

/s/ STEVEN GOULDEN
Acting Corporation Counsel

Date: October 19, 2023